DATE OUT: 08/05/09

SUBJECT: FEE   PRODUCT CHEMISTRY REVIEW OF MP [ ]   EP [X]
DP BARCODE No.: D367597   **REG. No. /File Symbol No.** 56799-G (containing unregistered source of AI)
PRODUCT NAME: OSKU-HELLAS
PCC: 078201   **Decision No.** 219583
FOOD USE   [X]
COMPANY: PRODUCTOS QUIMICOS Y AILMENTICIOS OSKU S.A

FROM: Indira Gairola, Chemist
Product Chemistry Team
Technical Review Branch/RD (7505P)

TO: Bryant Crowe/ Tony Kish PM 22
Fungicide Branch/RD (7505P)

INTRODUCTION:

PRODUCTOS QUIMICOS has submitted additional data for the subject product OSKU-HELLAS as recommended by TRB Please refer to the review dated 05/22/09 by Indira Gairola Under DP Bar Code 364738.
The submitted package was reviewed and details will be discussed below:

SUMMARY OF FINDINGS:

1. The subject product OSKU-HELLAS contains 73.5% of Anhydrous Sodium Bisulfite

2. PRODUCTOS QUIMICOS has submitted Enforcement Analytical Method MRID #s 477975-01, 478086-01 and -02 for Product Chemistry data to support the registration of OSKU-HELLAS.

3. The source of active ingredient for the subject product is unregistered.

4. Basic CSF dated 03/05/09 for the subject product meets the label claim of 73.5% of Anhydrous Sodium Bisulfite.

5. Data corresponding Sub Group A satisfy the data requirements of 40CFR§158.320

6. Product chemistry data for Sub group A and Sub group B for the unregistered Technical Sodium Bisulfite were reviewed and there are several data gaps remaining.

7. Product Chemistry Data for the Sub Group B for the proposed New Product have not been satisfied completely. Data for guideline series 830.6315 to 830.6317, 830.6320, 830.7000 and 830.7300 have not been satisfied. It is stated that Storage stability / corrosion characteristics study data for 20 month period were observed. No results of actual % of recovery for Anhydrous Sodium Bisulfite are included. Data for 3, 6, 9 and 12 month intervals are a requirement.

CONCLUSIONS:

TRB has reviewed the product chemistry data submitted for the above mentioned subject product and has concluded that:

1. The subject product OSKU-HELLAS contains 73.5% of Anhydrous Sodium Bisulfite.

2 The label claim is in compliance with PR Notice 91-2.

3. Basic CSF dated 03/05/09 for the subject product meets the label claim of 73.5% of Anhydrous Sodium Bisulfite will be accepted subject to the pending registration of the source of Technical.

4. The product chemistry data requirements for series 830 Sub Group A &B for the proposed new product are not satisfied. Based on the data gaps addressed in the Technical Product of Sodium Bisulfite the product chemistry data requirements are incomplete. Data gaps for the subject product that need to be addressed.

BARCODE No.: D367597 **File Symbol No.:** 56799-G **PRODUCT NAME:** OSKU-HELLAS

PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A & Subgroup B)Subgroup A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (Basic CSF)	A	Basic dated 03/05/09
830.1600. Beginning Materials	A	476996-02
30.1650. Formulation Process	A	476996-01
830.1670. Discussion of Impurities	A	476996-03
830.1700. Preliminary Analysis	NA	
830.1750. Certified Limits (Basic CSF)	A	Basic dated 03/05/09
830.1800. Enforcement Analytical Method	A	477975-01

PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup B)	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
830.6302. Color	A	white	Unassigned
830.6303. Physical State	A	Solid crystals	Unassigned
830.6304. Odor	A	Pungent SO2 odor	Unassigned
830.6314. Oxidation/Reduction Action	A	No visible reaction with Tetrahydrofuran,SO_2 is released with water, no visible reaction with KMnO4 Zn; Methanol,, Hexane & Methylene chloride	478086-01
830.6315. Flammability	G	Not stated	
830.6316. Explodability	G	Non stated	
830.6317. Storage stability	I	I	
830.6319. Miscibility	A	Water solubility 45% @ 20°C	Unassigned
830.6320. Corrosion Characteristics	I	I	
830.6321. Dialect. Bkd. Vltg.	NA		
830.7000. pH	U	Acidic specify range.	Unassigned
830.7100. Viscosity	N/A		
830.7300. Density/Bulk Density	U	Specific gravity 1.5 specify units	Unassigned

Explanations: Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.